IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of Stamm et al

Application No. 10/665,522

Filed: September 22, 2003

For: Fenofibrate Composition Having Enhanced Bioavailability

Docket No: 107664.115US13

Commissioner of Patents PO Box 1450 Alexandria, VA 22303-1450

Information Disclosure Statement

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicants bring to the attention of the Examiner the documents listed on the attached PTO-1449 Form.

The submission of this Information Disclosure Statement does not represent that a search has been made and does not constitute an admission that the listed documents and/or European Oppositions are material to patentability or that the listed documents are prior art.

This Information Disclosure Statement is being filed before the mailing date of a first office action on the merits and before a notice of allowance. Accordingly, no fee is due. The Commissioner is authorized to charge any necessary fees or credit any overpayments to Deposit Account No. 08-0219.

Applicants respectfully request that the Examiner initial and return a copy of the enclosed PTO-1449 Form with the next communication from the Patent Office.

Registration No

Respectfully submitted

Date: July 20, 2005

WILMER CUTLER PICKERING HALE AND DORR LLP

1455 Pennsylvania Avenue, NW

Washington, DC 20004 Phone: (202) 942-8453

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Substitute for form 1449/PTO

Sheet 1

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number 10/665,522

Filling Date September 22, 2003

First Named Inventor Stamm

Art Unit Examiner Name

Attorney Docket Number 107664.115 US13

			U. S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (fl known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 4,344,934	08-17-1982	Martin et al	
		^{US-} 2005/0032878 A1	02-10-2005	Deboeck et al	
		^{US-} 4,961,890	10-09-1990	Boyer	
		^{US-} 6,159,499	12-12-2000	Seth	
	<u> </u>	^{US-} 6,207,198 B1	03-27-2001	Seth	
		^{US-} 6,248,355 B1	06-19-2001	Seth	
		^{US-} 4,795,643	01-03-1989	Seth	
		^{US-} 5,824,341	10-20-1998	Seth et al	
		^{US-} 6,096,341	08-01-2000	Seth	
		^{US-} 6,033,686	03-07-2000	Seth	
		^{US-} 6,048,547	04-11-2000	Seth et al	
		^{US-} 6,117,453	09-12-2000	Seth et al	
		^{US-} 6,348,469 B1	02-19-2002	Seth	
		^{US-} 4,436,743	03-13-1984	Schonafinger et al	
		US- 4,716,033	12-29-1987	Denick, Jr.	
		^{US-} 4,558,058	12-10-1985	Schonafinger et al	
		^{US-} 4,957,746	09-18-1990	Valducci	
		^{US-} 4,806,361	02-21-1989	Harrison et al	
		^{US-} 4,820,521	04-11-1989	Panoz et al	

		FORE	IGN PATENT DOCU	IMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code ³ "Number ⁴ "Kind Code ⁵ (<i>if known</i>)	MM-DD-YYYY		Or Relevant Figures Appear	T ⁶
		WO 96/21439	07-18-1996	Galephar P.R. Inc.		
		WO 03/013500	02-20-2003	Laboratoires SMB SA		
		EP 0 012 523	06-25-1980	American Home Products		
		WO 97/12580	04-10-1997	Pharma Pass		
		EP 0 179 583	04-30-1986	Merck & Co.		
		EP 0 193 958	09-10-1986	PPG Industries, Inc.		

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Signature			Considered
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO		Complete if Known
	Application Number	10/665,522
INFORMATION DISCLOSURE	Filing Date	September 22, 2003
STATEMENT BY APPLICANT	First Named Inventor	Stamm \$100 Pt. April 100 Pt.
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(Use as many sheets as necessary)	Examiner Name	
Sheet 2 of 4	Attorney Docket Number	107664.115 US13

Examiner	Cite	NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	
Initials*	No.1	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Opposition to EP 952 829 by Winthrop Arzneimittel GmbH filed March 31, 2005.	
		Opposition to EP 952 829 by Laboratoires SMB S.A. filed April 11, 2005.	
		Papers filed on April 15, 2005, by Ethypharm in Response to Patent Proprietor's Statement for Opposition to EP 952 829.	
		Guichard et al, "A New Formulation of Fenofibrate: Suprabioavailable Tablets," Current Medical Research and Opinion, 16(2):134-138 (2000).	
		Kuchiki et al, "Stable Solid Dispersion System Against Humidity," Yakuzaigaku, 44(1):31-37 (1984).	
		Pharmaceutical Pelletization Technology, Ghebre-Sallassie, Ed., Marcel Dekker, Inc., New York, Chapters 7 & 10 (1989).	
		Giunchedi et al, International Journal of Pharmaceutics, 130:41-47 (1996).	
		Shah et al, International Journal of Pharmaceutics, 125:99-106 (1995).	
		Suzuki et al, Chem. Pharm. Bull. 49(4):373-378 (2001).	
		Sangalli et al, Boll. Chim. Farmaceutico, 128(7-8):242-247 (1989).	

Examiner	Date	***
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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Sheet 3

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(Use as many sheets as necessary)

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Application Number	10/665,522	
Filing Date	September 22, 2003	
First Named Inventor	Stamm	20, 44
Art Unit		
Examiner Name		
Attorney Docket Number	107664 115 US13	8,447

			U. S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ^{2 (ff known)}			rigules Appeal
		^{US-} 4,663,150	05-05-1987	Panoz et al	
		US-			
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		WO 96/04892	02-22-1996	Pharma Pass		
		EP 0 122 077	10-17-1984	Elan Corp.		
		EP 0 164 959	12-18-1985	Sterwin AG		
		EP 0 168 360	01-15-1986	Valducci		
		EP 0 239 541	09-30-1987	Warner-Lambert Co.		
		EP 0 256 933	02-24-1988	Ethypharm		

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Signature	Considered			
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STATEMENT BY APPLICANT	First Named Inventor	Stamm
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Sheet 4 of 4	Attorney Docket Number	107664.115 US13

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		European Pharmacopoeia, 3rd Edition, pages xiii-xvii and 127-131 (1996).	
		Remington's Pharmaceutical Sciences, 18th Edition, pages 1633-1665 (1985)	
		Handbook of Pharmaceutical Excipients, 2nd Edition, pages 48-87, 141-144, 229-232, 252-261, 280-282, 392-401, 424-427, 448-450, 462-469, 491-493 (1994).	
		The United States Pharmacopoeia, Vol. 23, pages liv-lvi, 1791-1793, 1924-1938 (1994).	
		International Dictionary of Medicine and Biology, Volume 2, page 1774, John Wiley & Sons, Inc. (1986).	
		Boullay, "Microgrinding and Dissolution," S.T.P. Pharma, 1(4):296-299 (1985). (French-language document and English-language translation)	~
		CRC Handbook of Chemistry & Physics, 73rd Edition, Chapter 15, Page 32 (1992).	

Examiner	Date	· · · · · · · · · · · · · · · · · · ·
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